K 081424

510(K) Summary

MAR 19 2009

Submitter:	Cynosure, Inc. 5 Carlisle Road Westford, MA 01886
Contact:	George Cho Senior Vice President of Medical Technology
Date Summary Prepared:	May 16, 2008
Device Trade Name:	Affirm CO_2 and Affirm CO_2 HP lasers
Common Name:	Medical Laser System
Classification Name:	Instrument, surgical, powered, laser 79-GEX 21 CFR 878.4810
Equivalent Device:	Smart CO_2 laser and SmartXide CO_2 with DOT Scanner laser
Device Description:	Affirm CO_2 and Affirm CO_2 HP lasers are CO_2 laser, having CO_2 gas as the lasing medium. It is a laser with a wavelength of 10.6 μm. Laser activation is by foot switch. Overall weight of the laser is 25 Kg, and the size is 180x62x42 cm (HxWxD). Electrical requirement is 110 VAC, 15A, 50-60 Hz, single phase.
Intended Use:	Affirm CO_2 and Affirm CO_2 HP lasers are indicated for incision, excision, and coagulation of body soft tissue.
Comparison:	The Affirm CO_2 and Affirm CO_2 HP lasers are substantially equivalent to the Smart CO_2 laser and the SmartXide CO_2 with DOT Scanner laser, with the same principle of operation, the same wavelength and essentially the same power range as the predicate devices for the same indications for uses.
Nonclinical Performance Data:	none
Clinical Performance Data:	none
Conclusion:	The Affirm CO_2 and Affirm CO_2 HP lasers are another safe and effective device for body soft tissue applications.
Additional Information:	none

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Cynosure, Inc.
% Mr. George Cho
Senior Vice President of Medical Technology
5 Carlisle Road
Westford, Massachusetts 01886

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Re: K081424
Trade/Device Name: Affirm CO_2 and Affirm CO_2 HP lassers
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: March 13, 2009
Received: March 16, 2009

Dear Mr. Cho:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 081424

Device Name: Affirm CO_2 and Affirm CO_2 HP lasers

Indications For Use:

The Affirm CO_2 and Affirm CO_2 HP lasers with SmartScan scanner are indicated for incision, excision, ablation, vaporization, and coagulation of body soft tissue including intraoral tissues, in medical specialties including aesthetic (dermatology and plastic surgery), otolaryngology (ENT), gynaecology, neurosurgery, dental, and oral surgery and genitourinary surgery. The use with the scanning unit is indicated for ablative skin resurfacing.

Prescriptive Use X OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081424